REMARKS

Claims 1-25 are pending in the captioned application.

Obviousness Rejection

Claims 1-25 were rejected under 35 USC §103(a) as being unpatentable over Lee in view of Friend, US Pat. No. 6,139,865). (20040628 ("Office Action" at 2.)

For the reasons set forth below the rejection, respectfully is traversed.

Lee discloses a chewable tablet a core containing a medicament in a state of jelly or chewable base; and an outer layer of chewable base wrapping the core. (Col. 1, ln. 65 – col. 2, ln. 3.) Lee discloses that a conventional chewable tablet has problems to take because of granular chew and chalky taste in the mouth where the invention "has a good taste and nice chewing property." (Col. 1, lines 33-35 and 46-52.) The medicament in the core was disclosed as being of bitter taste. (Col. 2, lns. 4-5.) Acetaminophen was disclosed as possibly being contained in the core. (Col. 2, lines 9-18.) According to Lee, the jelly base of the core, which contains the above medicament in a state of jelly, may be selected from the group consisting of pectin, sorbitol, maltitol, isomalt, liquid glucose, sugar, citric acid and a flavoring agent. (Col. 2, lns 29-32.) According to Lee, the chewable tablet provides taste mask effect to a bitter tasty medicament, which is contained in the medicament, and better chewing property and taste than the conventional tablets by means of an outer tasty chewable base. (Col. 3, lns. 54-57.)

Friend discloses a taste-masked microcapsule composition for administration of a drug. (Abst.) The drug is coated using a coacervation technique in which the drug is coated with relatively high levels of a polymeric material. (Abst.) The technique involves three phases: the core material phase of the drug to be encapsulated, a coating phase of the drug coating substance and a liquid phase in which the core and the coating materials are dispersed or dissolved. (Col. 1, lns. 54-60.) Data are provided that show average and median scores for microencapsulated ranitidine tablets for taste masking, bitterness, aftertaste and overall acceptance. Figs. 3A-3D and 4A-4D. According to Friend, the particle size of the microcapsules can be in the range of a few microns to a thousand microns or more. (Col. 8, lines 31-36.)

In making the rejection, the Examiner asserted that "Lee teaches a chewable pharmaceutical dosage form comprising a core containing an active ingredient and an outer layer." (Paper No. 20031222 at 2.) The Examiner contended that "the dosage form demonstrates improved organoleptic properties when chewed, such as taste. (*Id.*) The Examiner asserted that the "core may be in the form of a jelly, with the base of the jelly selected from a group that includes pectin. The Examiner further asserted that gelatin may be used in either the core or outer layer to maintain hardness and extension property in the dosage form. The

Examiner stated that the "outer layer may take a variety of forms, including hard candy and that acetaminophen is listed as a possible active ingredient in core. The Examiner concluded that Lee contains and enabling disclosure of a dosage form with a unitary core.

The Examiner contended that Friend "teaches taste-masked microcapsule compositions for the administration of a drug," including acetaminophen and ibuprofen. (Paper No. 20031222 at 3.) The Examiner further contended that Friend discloses that "[t]he compositions may be incorporated into a variety of dosage forms, including chewable tablets, in amounts ranging from 10% to 95% by weight of the dosage form." The Examiner further asserted that Friend discloses that "preferred [] microcapsules range in size from approximately 30 microns to 800 microns."

The Examiner asserted that both Lee and Friend "deal with the administration of drugs in pharmaceutical compositions with improved organoleptic properties." The Examiner reasoned that "one of ordinary skill would be motivated to incorporate the composition disclosed in Friend into the dosage form of Lee in order to provide a pharmaceutical dosage form wherein the active ingredient is further taste-masked without an undue delay on the release of the drug." The Examiner then concluded that "it would have been obvious to one of ordinary skill in the art to combine the teachings of Lee and Friend into the objects of the instant application. (Paper No. 20031222 at 3.)

The Examiner then opined that "[a]s Friend states that the disclosed compositions may be incorporated in chewable tablets, it is the position of the Examiner that one of ordinary skill in the art could combine the disclosures of the prior art with a reasonable expectation of success."

The Examiner cited *In re McLaughlin*, 443 F.2d 1392 (CCPA 1971) for the proposition that an obviousness analysis "is in a sense necessarily a reconstruction based on hindsight reasoning." (Office Action at 2.)

The Examiner also took the position that the affirmative texture masking limitation added to the claims in the April 15, 2004 Response is "implicit and/or inherent in the broad combined disclosure of the prior art." (*Id.*)

1. Examiner used an Incorrect Standard for Obviousness Rejection

The determination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention. For a *prima facie* case of obviousness to be established, it is well settled that the teachings from the prior art itself must appear to have suggested the claimed subject matter to one of ordinary skill in the art at the time the invention was made. The mere fact that the prior art could be

modified as proposed by the Examiner is not sufficient to establish a *prima facie* case of obviousness.

In setting forth the analysis for the instant rejection, the Examiner appears to have fallen into the trap of hindsight reconstruction. This is because the record memorializing the Examiner's analysis of the grounds of rejection is based solely on current knowledge. The record does not indicate that the Examiner undertook any analysis that was placed at the time the invention was made. For example, the Examiner stated that "[i]t would have been obvious to one of ordinary skill in the art to combine the teachings of Lee and Friend into the objects of the instant application." (Paper No. 20031222 at 3.)

Such a time limitation in conducting an obviousness inquiry is a necessary protection to prevent the Examiner from falling into the powerful attraction of conducting hindsight-based obviousness analysis. Nonetheless, the Examiner has succumbed to this attraction and used hindsight reconstruction to make out the rejection. For this reason alone, the rejection is improper and should be withdrawn.

2. It Appears that the Examiner Improperly Analyzed the "Objects of the Instant Application" – Not the Claims

Not only does it appear that the Examiner's analysis was not based on at the time the invention was made, but the Examiner appears to have analyzed the "**objects of the instant application**" With all due respect, it is the claims that are analyzed – not the "objects" of the instant invention.

Here, not only has the Examiner applied the wrong legal standard, which, it is submitted, is reason enough for withdrawal of the rejection, but the Examiner also has ***not even alleged*** that the claimed subject matter would have been obvious and, therefore, has not met his burden required to support a *prima facie* case of obviousness. See *Ex parte Obukowicz*, 27 USPQ2d 1603, 1605 (BPAI 1992). For these further reasons, it respectfully is submitted that the rejection should be withdrawn.

3. Claimed Subject Matter is Not Inherently Disclosed by the Cited Documents

Texture masking was added as an affirmative limitation to the claimed subject matter in the April 15, 2004 Response. The Examiner contended that such a limitation is "implicit and/or inherent in the broad combined disclosure of the prior art."

It is well settled that "that which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown." *In re Spormann*, 150 USPQ 449, 452 (CCPA. 1966). Inherency, however may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. *In re*

Oelrich, 212 USPQ 323, 326 (CCPA 1981) (quoting *Hansgirg v. Kemmer*, 40 USPQ 665, 667 (CCPA 1939): Nonetheless, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. *Ex parte Levy*, 17 USPQ 2d 1461, 1464 (BPAI 1990) When the PTO asserts that there is an explicit or implicit teaching or suggestion in the prior art, it must indicate where such a teaching or suggestion appears in the prior art (citing *In re Yates*, 663 F.2d 1054, 1057, 211 USPQ 1149, 1151 (CCPA 1981). *In re Rijckaert*, 9 F.3d 1531, 1533, 28 USPQ 2d 1955, 1957 (Fed. Cir. 1993)).

The Examiner asserted that the "prior art has disclosed the same composition structure, the same components, and the same particle sizes as that claimed by applicant." With all due respect, it is not seen where the Examiner's assertion is supported by the record in the captioned case. For example, it is the Examiner's position that "the cited documents affirmatively disclose the same particle size as that claimed by the applicant".

By way of background, the independent claims of the captioned application are directed to, among other things, "a plurality of active agent particles having an average size of greater than 50 μm." It is not seen where Lee discloses any particle size for anything, much less the claimed average particle size of the active agent particles. Friend discloses particular particle sizes for **microcapsules**, see e.g., col. 8, lns. 31-36. Table 1 and Table 2 in Friend appear to disclose that the mean particle size for ranitidine from Glaxo as being granular. It is unclear what specific particle size "granular" is intended to cover. Due to the lack of any specific guidance as to what "granular" is intended to mean, it is not seen where a disclosure of "granular" discloses the claimed active agent particle sizes. Furthermore, the Examiner has not provided any specific reason why one skilled in the art would reasonably infer that the affirmatively claimed active agent particle sizes would be disclosed by a "granular" form of ranitidine hcl from Glaxo. For this reason, the rejection is improper and should be withdrawn.

By way of an additional example, it is the Examiner's position that "the same composition structure as that claimed by the applicant" is affirmatively disclosed by the cited documents. However, it is not seen in this record where there is any disclosure or suggestion for the claimed weight ratio of active agent particles to shell. For this additional reason, the rejection is improper and should be withdrawn.

In Paper No. 20031222, the Examiner opined that the burden shifted to the applicant to demonstrate how the weight ratio of active agent particles to the outer shell, among other things, are critical features. (*See* p. 3.) First, the burden only shifts to the applicant when a prima facie rejection has been made. Because there has been no prima facie case of obviousness made in

this record, there has been no shift in the burden. The burden still lies with the Examiner. Second, as discussed above, the Examiner most recently took the position that the cited documents disclose "the same composition structure as that claimed by the applicant." Such composition structure includes, but is not limited to, the claimed weight ratio. For this reason, the burden has not shifted from the Examiner.

4. Cited Documents are Not Properly Combinable

The Examiner reasoned that "one of ordinary skill would be motivated to incorporate the composition disclosed in Friend into the dosage form of Lee in order to provide a pharmaceutical dosage form wherein the active ingredient is further taste-masked without an undue delay on the release of the drug." (Paper No. 20031222 at 3.) The fact that Friend discloses "that the disclosed compositions may be incorporated into chewable tablets" provided the springboard for the Examiner to opine that "one of ordinary skill in the art could combine the disclosure of the prior art with a reasonable expectation of success." (*Id.*)

One of the advantages of Lee's invention was the alleged "excellent stability." The Examiner's attention is directed to column 3, lines, 31-53. In this passage, Lee describes the fact that "the chewable tablet of the present invention is prepared by the process in which the [drug] is mixed with the jelly or a chewable base at room temperature." Such preparation was, according to Lee, the reason why Lee's chewable tablet had "excellent stability."

Contrary to Lee's room temperature method, Friend heats a mixture to 80°C until all of the polymer is dissolved, adds the drug to the polymer mixture, and stirs at 450 rpm for 1 hour. (Friend, col. 11, Example 1.) The resulting mixture was then allowed to cool with stirring at 450 rpm at about 0.5°C/min for 1 hour to a final temperature of about 50°C. (*Id.*) Friend further cautions that "care must be taken not to heat to a temperature which could degrade the drug." (Col. 5, lns. 31-32.)

It is not seen where one of ordinary skill in the art would be motivated to further taste mask a drug by applying heat in the process of making the final product where Lee's invention specifically states that the chewable tablet formulation has "excellent stability" because it is produced at room temperature. It appears that Lee teaches away from Friend. For this reason, it is not believed the cited documents are properly combinable and the rejection should, therefore, be withdrawn.

Finally, the Examiner is invited to call the applicants' undersigned representative if any further action will expedite the prosecution of the application or if the Examiner has any suggestions or questions concerning the application or the present Response. In fact, if the claims of the application are not believed to be in full condition for allowance, for any reason,

the applicants respectfully request the constructive assistance and suggestions of the Examiner in drafting one or more acceptable claims pursuant to MPEP § 707.07(j) or in making constructive suggestions pursuant to MPEP § 706.03 so that the application can be placed in allowable condition as soon as possible and without the need for further proceedings.

Accordingly, for the reasons set forth above, entry of the amendments, withdrawal of the rejections, and allowance of the claims is respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

Respectfully submitted,

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Dated: August 19, 2004
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